REMARKS

The Final Office Action mailed June 4, 2002 has been received and reviewed. Claims 1-5, 9 and 20-24 are pending in the application and all claims stand rejected. Applicants propose to amend claims 1 and 2 and cancel claim 9 as set forth herein. All amendments, including the cancellation of claim 9, are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1-5, 9 and 20-24 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification assertedly does not reasonably provide enablement for the pending claims. Claims 1-5, 9 and 20-24 were also rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Applicants propose to amend claims 1 and 2 as set forth herein and in view thereof, respectfully traverse the rejections. Claim 9 has been cancelled rendering the rejection thereof moot.

In particular, the Final Office Action asserted that the specification does not reasonably provide enablement for any peptide, any immunogenic polypeptide, any analog, and any derivative thereof having up to 15 amino acids constituting a T cell epitope obtainable from minor Histocompatibility antigen HA-1. (Final Office Action, page 2). Although applicants do not agree that the claims are not enabled, applicants propose to remove the phrase "a derivative thereof having similar functional or immunological properties" from claims 1 and 2.

In view of the proposed amendments, the claims are enabled since the application discloses that mHag HA-1 specific CTLs can be generated *ex vivo* with the claimed peptide and immunogenic peptide of claims 1 and 2, respectively. Further, the claimed peptides can be functionally presented to the immune system in the context of a MHC class I molecule. Thus, the claimed peptide and immunogenic peptide with the sequence VLXDDLLEA (SEQ ID NO:1) are capable of being presented by a MHC class I molecule and are within the scope of the present invention.

The Final Office Action also asserted that the term "comprising" in claims 1 and 2 rendered the claims unpredictable since the claimed peptide or immunogenic polypeptide may include additional amino acids on either end of SEQ ID NO: 1 that may read on MHC class II peptides. (*Id.* at page 4.) It was further asserted that "[b]ecause of the indefinite number of amino acids that may be encompassed in the polypeptide of instant claims and there is no disclosure about the structure associated with functions of *any* polypeptide, it is not clear a polypeptide 'comprising' SEQ ID NO: 1 would have similar functional or immunological properties." (*Id.*).

As proposed to be amended, claims 1 and 2 are limited to a peptide or an immunogenic peptide constituting a T-cell epitope obtainable from the minor Histocompatibility antigen HA-1 ~~having up to 15 amino acids~~ comprising the sequence VLXDDLLEA (SEQ ID NO:1). Since it is known that MHC class I molecules are capable of associating with peptides of varying length, one of skill in the art would be able to make and use a peptide or immunogenic peptide constituting a HA-1 epitope using the teachings of the present invention. Thus, claims 1 and 2 comply with the requirements of 35 U.S.C. § 112, first paragraph.

Regarding dependent claims 4, 5 and 21-24, the Final Office Action indicated that the claims were not enabled since the specification fails to provide any guidance and *in vivo* working examples as to vaccines and pharmaceutical formulations comprising the immunogenic polypeptide which would prevent Graft versus Host disease or be able to treat HA-1 related autoimmune disease. (*Id.* at page 5).

"If a statement of utility in the specification contains with it a connotation of how to use, and/or the art recognizes that standard modes of administration are known and contemplated, 35 U.S.C. 112 is satisfied." (M.P.E.P. § 2164.01(c)). Thus, since the as filed application discloses a connotation of how to use the peptides of the present invention as a vaccination or pharmaceutical formulation (*See*, Specification, page 7, line 25 through page 8, line 25) and standard modes of administering vaccines and pharmaceutical formulations are well known in the art, claims 4, 5 and 21-24 are enabled.

With regard to dependent claims 3 and 20, they are enabled as depending from enabled claims 1 or 2.

Accordingly, reconsideration and withdrawal of the enablement rejections of claims 1-5 and 20-24 are respectfully requested.

Claims 1-5, 9 and 20-24 were further rejected under 35 U.S.C. § 112, first paragraph, as a new matter rejection since the claims assertedly contain subject matter which was not described in the specification is such a way to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Applicants respectfully traverse the new matter rejections.

The Office Action indicates "[t]he 'up to 15 amino acids' in Claims 1, 2 and 9 represents a departure from the specification and the claims as originally filed." (Final Office Action, page 9). Since the as filed specification clearly disclosed that the peptides of the present invention may be up to 15 amino acids in length, the addition of the phrase "up to 15 amino acids" to the claims is not new matter.

"Information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." (M.P.E.P. § 2163.06). Therefore, since the as filed specification clearly states "peptides presented in such a context vary in length from about 7 to about 15 amino acid residues" and "the upper length of a peptide provided by the invention is no more than 15 amino acids," the addition of the phrase "up to 15 amino acids" to the claims cannot be deemed new matter. (Specification, page 6, lines 27-32).

Accordingly, reconsideration and withdrawal of the new matter rejections of claims 1-5 and 20-24 are respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1-5, 9 and 20-24 also stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The rejection of claim 9 is moot in view of the cancellation thereof. Applicants propose to amend claims 1 and 2 as set forth herein, and in view of the proposed amendments respectfully traverse the rejections.

Specifically, the phrase "having similar functional or immunological properties" of claims 1, 2 and 9 was thought to be indefinite. Although applicants do not agree that the claims are indefinite, for the sake of expedited prosecution, the phrase "or a derivative thereof having similar functional or immunological properties" is proposed to be removed from claims 1 and 2 rendering the indefinite rejections moot.

Accordingly, reconsideration and withdrawal of the rejections of claims 1-5 and 20-24 are respectfully requested.

Rejections under 35 U.S.C. § 102

Claims 1-2, 4-5, 9, 21 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Haan et al. (Eur J Immunol 26:2680-2685, 1996; PTO 892). Claim 9 has been cancelled rendering the rejection of the claim moot. Applicants propose to amend claims 1 and 2 and in view thereof respectfully traverse the rejections.

The proposed amendments remove the phrase "a derivative thereof having similar functional or immunological properties" from claims 1 and 2. Accordingly, claims 1 and 2 are directed to a peptide or an immunogenic peptide, respectively, comprising the sequence VLXDDLLEA (SEQ ID NO: 1). Since the Haan et al. reference does not disclose a peptide with SEQ ID NO: 1, it cannot anticipate claims 1 and 2.

Reconsideration and withdrawal of the anticipation rejections of claims 1 and 2, and claims 4-5, 21 and 23 depending therefrom are thus requested.

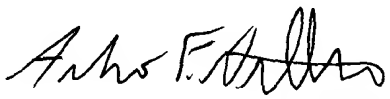
ENTRY OF AMENDMENTS

The proposed amendments should be entered because they are supported by the as-filed specification and drawings and do not any new matter to the specification. Since the amendments comply with requirements to form set forth in the Final Office Action and further place the application in condition for allowance, the amendments should be entered. If the amendments do not place the application in condition for allowance, entry is respectfully requested since they certainly remove issues for appeal.

CONCLUSION

In view of the amendments and remarks presented herein, applicants respectfully submit that the amended claims define patentable subject matter. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



Andrew F. Nilles
Registration No. 47,825
Attorney for Applicant(s)
TRASKBRITT
P.O. Box 2550
Salt Lake City, Utah 84110-2550
Telephone: 801-532-1922

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AFN/afn
Document in ProLaw

MARKED UP VERSION OF CLAIMS SHOWING CHANGES MADE

1. (Thrice amended) A peptide having up to 15 amino acids constituting a T-cell epitope obtainable from the minor Histocompatibility antigen HA-1, said peptide comprising the sequence VLXDDLLEA (SEQ ID NO:1) [or a derivative thereof having similar functional or immunological properties], wherein X represents a histidine or an arginine residue.

2. (Thrice amended) An immunogenic polypeptide having up to 15 amino acids obtainable from the minor Histocompatibility antigen HA-1, said immunogenic polypeptide comprising the sequence VLXDDLLEA (SEQ ID NO:1) [or a derivative thereof having similar functional or immunological properties], wherein X represents a histidine or an arginine residue.